UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 6, 2017

Danielle A. Larochelle
Regulatory Manager
Nufarm Americas Inc.
4020 Aerial Center Parkway, Suite 101
Morrisville, NC 27560

Subject: Antibiotics: Oxytetracycline calcium Petition 6E8539 for use on sweet and tart cherries
Product Names: Mycoshield, Oxytetracycline Calcium Technical
Petition Number: 6E8539
EPA Registration Numbers: 55146-97, 55146-99
Receipt date: 12/19/2016
Decision Numbers: 524640, 524637, 524629

Dear Ms. LaRochelle:

Thank you for joining us on March 27, 2017 to discuss Nufarm America's Inc current antibiotic applications in house, specifically petition 6E8539 for oxytetracycline calcium. During this conversation the Agency identified certain data for all pending antibiotic applications that we believe will help us to move forward towards making a decision on these types of applications. These data/information include the following:

1. Robust benefits (grower and economic) information, including alternatives information for each proposed new use
2. Robust efficacy data on each proposed new use, submitted as a separate document if possible
3. A robust 152 assessment. If references/citations to literature are included in the 152 assessments, please provide these references.
4. Details of current/proposed stewardship/resistance management plans regarding antibiotic resistance management
5. Updated draft labels incorporating resistance management language including items such as FRAC code/best management practices (see PRN 2001-5), lack of performance reporting, etc. Please note there is also new draft guidance for pesticide resistance available at https://www.epa.gov/pesticide-registration/prn-2016-x-draft-guidance-pesticide-registrants-pesticide-resistance.
6. Any monitoring data that you may have available. If you have already submitted monitoring data to the Agency, please reference MRIDs and dates of submission. Further monitoring may be required as a condition of registration and monitoring by a third party would be preferable.
7. Co-selection/cross resistance data (see note below).

We understand that some of the above listed items have been previously provided. However, if you have any updates to the previously submitted information and/or new information to satisfy the items 1-6 above, please submit the data/updates by 6/1/2017, as receipt of this in an expeditious manner will facilitate the Agency in making progress towards meeting the PRIA due date.

At this time the Agency is not requesting that you submit information for item 7 or cite testing for co-selection or cross resistance potential in human isolates. The Agency's current plan is to coordinate with the Centers for Disease Control to obtain this information.

Educational and training materials for growers and users may be necessary in order for the Agency to ultimately find that your applications meet the no unreasonable adverse effects standard. These materials may include resistance-management plans, remedial-action plans, and other educational and training materials on antibiotic resistance and its management. In general, these plans should be easily modifiable to adapt to changing conditions and to account for local situations. The Agency may recommend that registrants work with agricultural extension, crop consultants, individual crop associations, the Fungicide Resistance Action Committee, and the U.S. Department of Agriculture in developing these plans.

As the Agency continues to review these PRIA actions, we may have additional label revisions that will need to be incorporated into the affected labels.

If you have any questions, please contact me by phone at 703-305-5410, or via email at johnson.hope@epa.gov.

Sincerely,

Hope Johnson, Product Manager 21
Fungicide Branch
Registration Division (7505P)
Office of Pesticide Programs